

1 PQRI's proposal is -- we acknowledge that there are
2 problems with blend uniformity testing, and the data that
3 we did in the data mining showed that 20 percent of the
4 time that is occurring. We took that into account in our
5 whole approach by removing the emphasis for passing or
6 failing validation batches, let's say, by looking at both
7 the blend and the dosage uniformity data in conjunction,
8 putting further emphasis of the testing on the dosage
9 units, because let's face it, that's what's going to the
10 patient, not the blend -- we don't have sampling errors
11 with dosage units. We do have them with blend samples.
12 So, we are putting the emphasis on testing where it
13 belongs, on the actual dosage unit that's going to the
14 patient. That's what I'm saying.

15 DR. KIBBE: So, you're eliminating an
16 unreliable test by eliminating powder batch uniformity
17 testing.

18 DR. GARCIA: What we're saying is the best way
19 to assess the adequacy of mix of a blend is indirectly by
20 measuring the dosage units made from it. Does that clarify
21 it?

22 DR. LEE: I think that is the point that Art
23 was going after.

24 DR. KIBBE: Yes.

25 DR. GARCIA: The best way is an indirect

1 measurement of it.

2 DR. LEE: Judy?

3 DR. BOEHLERT: But during process validation,
4 testing of the blend is still in there, is it not? And if
5 indeed you've got all of these sampling problems, you're
6 not going to be able to validate your process.

7 DR. GARCIA: Go back to the first part of the
8 document, though. It says you should put adequate
9 development into your sampling technique.

10 DR. BOEHLERT: Where I was leading to is
11 perhaps there should be some language in the document that
12 gives allowance for using alternate technologies when you
13 run into that roadblock because you may not be able to
14 readily find a good alternate sampling technique and maybe
15 going to some on-line kind of test or some other means of
16 testing would be preferable.

17 DR. GARCIA: We do address that. We say in the
18 end other technologies are acceptable. So, we do address
19 that.

20 DR. BOEHLERT: We need to emphasize that so
21 it's clear.

22 DR. GARCIA: In the flow diagram, we say if the
23 blends fail the criteria we had listed there, perform an
24 investigation into why they failed. If it is a sampling
25 bias, then proceed on, whereas at the current state of

1 affairs, you don't proceed on if it is.

2 Now, we do feel that it is worthwhile to do
3 some sort of blend assessment during validation because we
4 don't want somebody just putting out -- you know, throw it
5 in a bag, shake it up a little bit, and then compress it.
6 We don't want anything poor going through.

7 DR. BOEHLERT: I absolutely agree. You need to
8 determine how long to mix and all of those good things.

9 DR. GARCIA: Right, but on a long-term routine
10 monitoring, no, you're better off testing the dosage units.

11 DR. LEE: I believe that the committee has
12 expressed a consensus, which is that we need to incorporate
13 the findings into a revised guidance, put it out there,
14 invite more hopefully data submissions. In the meantime,
15 we have a few moments to understand the implications of
16 this document, and by the time that we meet next time, we
17 should be able to maybe answer these very important
18 questions.

19 Pat and Nair, do you have anything to add?

20 DR. DeLUCA: No. I think I agree. Blending is
21 going to be part of the validation. It's a very important
22 aspect I think of understanding the mixing process.

23 DR. LEE: Okay. Nair?

24 DR. RODRIGUEZ-HORNEDO: Yes, I agree with what
25 has been said and particularly the fact that during the

1 blending operation, we may need to correlate the factors
2 that affect the blending in buying the materials from a
3 manufacturer. What are the specifications? I think
4 eventually the on-line monitoring is [inaudible].

5 I think what's confusing us throughout these
6 exercises is the term blending, standard deviation, RSD,
7 and the fact that at the current state of affairs, we
8 really are using very problematic sampling techniques.

9 DR. LEE: Thank you very much. I'll expect
10 both of you to blend in with the rest of us next time.

11 (Laughter.)

12 DR. DeLUCA: It will be a lot easier.

13 DR. LEE: Well, I'm glad that we changed the
14 agenda a little bit. In any event, I think that was a very
15 good discussion, and let's move on.

16 The next agenda item is to receive an update
17 from two subcommittees. The first subcommittee is the
18 Nonclinical Studies Subcommittee, and John Doull is going
19 to present the report. John, I think that you have about
20 5-10 minutes. Is that right?

21 DR. DOULL: Yes.

22 Well, some of you have in your agenda that Jim
23 MacGregor is going to present this report. He called me on
24 Monday and said he will be in NCTR for some other meetings
25 and couldn't do it. But he told me he's sending me a group

1 of slides. Unfortunately, my e-mail was sick all day
2 Monday and all day Tuesday. But Nancy has put together the
3 slides, and so I think we can do this fairly briefly.

4 Some of you may recall that in the July meeting
5 of this committee, we had invited Dr. William Kerns and Dr.
6 Gordon Holt to come and tell us what progress was being
7 made with the two working groups that have been appointed
8 under the subcommittee, the Cardiotoxicity Working Group
9 and the first one which we called initially Vasculitis.

10 After that presentation, there was some
11 discussion, led primarily by Jim MacGregor and Helen Winkle
12 and some members of the committee, concerning the role and
13 the management of the Nonclinical Studies Subcommittee.
14 And today I'm really here to bring you a progress report on
15 what has transpired since our July meeting, and I'm pleased
16 to tell you that both of these committees have been very
17 actively working since that time and also that they have
18 been involved, both of them, in inviting outside groups,
19 industry groups, professional groups, trade associations,
20 and other regulatory groups and so on.

21 I would point out that that is one of the goals
22 of the subcommittee, to find biomarkers that are useful for
23 preclinical evaluation of adverse effects. The second goal
24 is to look for biomarkers which are also useful clinically.
25 And the third goal is the goal to encourage cooperation

1 between industry, academia, and the regulatory agency.

2 I should say that the subcommittee met a couple
3 of weeks ago, and what these slides are essentially is a
4 summary report which came from that meeting. This is the
5 one from the Cardiotoxicity Group that Dr. Ken Wallace
6 presented. It's also been reproduced in your handout.

7 The main activity of the Cardiotoxicity Group
8 is that they organized a symposium. That symposium was
9 held at the American College of Toxicology. It was very
10 well attended and from everything I heard was very well
11 received. And it was on troponins, troponin T, troponin I.
12 Because of that then, the Cardiotoxicity Group is looking
13 forward to doing other symposia and joint workshops with
14 various other groups. They're talking to ILSI and some
15 other groups, as I understand it.

16 They would like to put together a proposal to
17 use troponins as a measurement, a biomarker for drug-
18 induced cardiotoxicity, and they're in the process of doing
19 that.

20 Now, they are, of course, looking at other
21 biomarkers for cardiotoxicity, but the initial focus was on
22 troponin. I think Helen described that as available fruit
23 from the tree.

24 MS. WINKLE: Low-hanging fruit.

25 DR. DOULL: Low-hanging fruit. That's it.

1 hopefully will come some useful biomarkers.

2 The final slides here have to do with timing.

3 They had hoped to get this protocol put together by
4 February, and if they've identified funding by that time,
5 then they would hope to go ahead and issue this RFI or
6 research protocol. They figure it will probably take a
7 year to get these studies done. That indicates that a year
8 later they would then begin to look and make some
9 recommendations regarding biomarkers for vascular injury.

10 The final two slides are the members of this
11 committee. You can see that they represent industry,
12 academia, and the regulatory agency.

13 As I indicated, our committee met a couple
14 weeks ago, and we reviewed briefly what they've done. But
15 we spent most of the time looking at ways in which the
16 subcommittee could support the momentum which had been
17 generated by both of our working groups. We talked about
18 funding. We talked about publication. We talked about the
19 management, the support areas. We talked about data
20 confidentiality. Although we didn't really solve any of
21 those problems -- in fact, we haven't really solved them
22 yet -- we are working on them, and I think many of the
23 answers, hopefully, that come out of our discussion will be
24 useful to other committees.

25 The issue of funding. We need to be able to

1 identify funds that could be used to support research. If
2 we have additional committees that have to do with imaging
3 or that have to do with genomics or proteomics, funding
4 would also be an issue for them.

5 The publication. Some members of the working
6 groups were concerned about the fact that if a committee
7 with the Food and Drug name on it makes a recommendation
8 about troponins, for example, what does that really mean in
9 terms of guidance, and I think we have to deal with that.

10 The third issue was the data confidentiality
11 issue, and that had to do with the working of the expert
12 working groups. In order to discuss confidential data
13 within those groups, they needed to make some internal
14 arrangements, and I think they've dealt with most of those.

15 The final issue had to do with reporting.
16 Right now the subcommittee reports to this committee and
17 the working groups report to the subcommittee. Once the
18 link to NCTR is developed, then the question is do we have
19 dual reporting or do we continue to report primarily to
20 this group. I think the members of both working groups
21 felt it's very advantageous to be able to report to this
22 group. We want this group to know if we are close to
23 developing biomarkers which would be useful in
24 cardiotoxicity or vascular injury.

25 Gloria, you were at our meeting. Did I miss

1 anything? We'll be glad to answer questions.

2 DR. LEE: We're approaching the time of
3 official adjournment.

4 Dr. Himmel, you wanted to ask a question?

5 DR. HIMMEL: No. I thought we were going on to
6 the next agenda item.

7 DR. LEE: Any questions for John?

8 (No response.)

9 DR. LEE: Very interesting. Biomarkers. I
10 think that's something on the horizon.

11 Dr. Himmel is going to report on behalf of the
12 Drug Safety and Risk Management Subcommittee.

13 MS. WINKLE: Can I say a few words before Marty
14 talks?

15 DR. LEE: Sure.

16 MS. WINKLE: When I showed the slide this
17 morning, I told you that this was a subcommittee that was
18 currently in the making, this Drug Safety and Risk
19 Management Committee. It's still up in the air, and
20 there's a lot of discussion in the agency on where this
21 committee will reside or whether it would be a subcommittee
22 out of this committee. I thought it would be important for
23 you all to hear about this group, though, and what they
24 plan to do, so if the decision is to move it under this
25 committee, we will already know the information and then we

1 can discuss it further if need be. So, I'll turn it over
2 to Marty with that, but I just wanted to give you an idea
3 of where we were, which is nowhere. They've got a good
4 idea, but we haven't made the final decisions on where it
5 will reside.

6 DR. LEE: Thank you, Helen.

7 DR. HIMMEL: Well, I think we're a little
8 beyond nowhere, but we're not there yet.

9 (Laughter.)

10 DR. HIMMEL: My name is Marty Himmel, and I'm
11 the Deputy Director for the Office of Postmarketing Drug
12 Risk Assessment. That's also called OPDRA, which I think
13 is easier to say, which is part of CDER. What we're
14 responsible for in CDER is post-marketing drug safety. So,
15 a lot of our work focuses on looking at the post-marketing
16 arena, looking for signals of safety problems, working with
17 the review divisions to develop risk management plans and
18 risk management approaches around drugs. Medication errors
19 is a big area as well, both in the pre-market looking at
20 trade names, as well as the post-market looking at safety
21 signals.

22 Over the past period of time, months to maybe
23 the past year or so, we've certainly recognized and the
24 center recognizes that there are a lot of complex issues
25 surrounding the types of things that we've been grappling

1 with, both drug-specific types of issues, how you develop
2 the best type of risk management program, how you deal with
3 some of the risk communication, risk perception issues, as
4 well as some of the methodologic issues that we're
5 grappling with, ranging from what should be appropriate
6 metrics for risk management, what should be appropriate
7 designs for looking for trial designs for anticipating
8 medication errors, a research agenda, and the like.

9 So, because those issues are quite complex,
10 we've recognized that there is value and there would be
11 need in getting outside expert advice in the context of an
12 advisory committee meeting or an advisory subcommittee
13 meeting where we could have some open public discussion of
14 that.

15 So, over the past few months, we've been
16 working at trying to craft just such a group. Again, as
17 Helen mentioned, we're not sure where that group is going
18 to reside just yet, but wherever it resides, the issues
19 that it's going to be dealing with and the type of
20 structure that it should have would be the same. So, what
21 we did was try to divide out the areas of expertise that we
22 think we'd particularly want to have on such a committee,
23 which is very new and unique to the center. So, we
24 targeted experts in pharmacoepidemiology, experts in risk
25 communication, risk perception, risk management, medication

1 errors, clinical trial methodologies, evidence-based
2 medicine, clinical pharmacology, and tried to identify
3 leaders in the field in each of those areas so that we
4 would have a couple of representatives that could speak to
5 each of those areas and help us as we grapple with a lot of
6 the issues.

7 At the present time, we've pretty much
8 identified the roster of people that would be on the
9 subcommittee. The paperwork is still in the works at this
10 point in time, so I can't really go into the names and who
11 is going to be on the subcommittee and so on.

12 Actually we were very encouraged and very
13 excited about the fact that everybody we spoke to out in
14 the community and out in academia was very enthusiastic and
15 excited about having this type of a committee or a
16 subcommittee that could start to grapple with a lot of
17 these issues in a very open and public way.

18 Again, we're waiting to get final decisions on
19 where the committee is going to reside. We do anticipate
20 that wherever it does reside, probably towards the
21 beginning of 2002, maybe the end of the winter or early
22 spring, we would anticipate having the group,
23 subcommittee/committee, up and running and dealing with
24 issues.

25 Again, as I mentioned, I would anticipate that

1 as we use the committee -- and we're going to have to learn
2 how to -- it will probably focus on two general areas:
3 drug-specific areas where the review divisions in the
4 center have some drug-specific safety issues that they're
5 grappling with, design of a risk management program and the
6 like. So, therefore we can combine with some of those
7 disease-specific advisory committees and help them deal
8 with those issues, as well as more broader range
9 methodologic types of issues which may not be drug-
10 specific, but which will give us input on how to devise
11 appropriate methodologies and approaches to some of the
12 safety issues that we're grappling with.

13 So, that's pretty much where we are right now.
14 We're pretty close to having the full complement of people.
15 I think we have a nice, broad range of expertise and are
16 anticipating being up and running in one form or another in
17 the beginning of the next year.

18 DR. LEE: Thank you very much.

19 Are there questions for Marty?

20 (No response.)

21 DR. LEE: I think you made an excellent, clear
22 presentation.

23 Well, that concludes today's discussions,
24 deliberations. Are there any other questions that anybody
25 wants to raise before we adjourn?

1 | (No response.)

2 DR. LEE: Well, if not, tomorrow is going to be
3 another interesting day. We are going to be starting the
4 day with dermatopharmacokinetics in the morning, and in the
5 afternoon individual bioequivalence.

6 Thank you. The committee members are now
7 invited to stay for the training session.

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